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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,909	12/12/2005	Boris Y. Shekunov	FER-14670.001.002	6194
7609 7590 04/15/2011 RANKIN, HILL, & CLARK LLP 23755 Lorain Road - Suite 200 North Olmsted, OH 44070-2224				
EXAMINER				
HAGOPIAN, CASEY SHEA				
ART UNIT		PAPER NUMBER		
1617				
MAIL DATE		DELIVERY MODE		
04/15/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

Applicant(s)

Examiner

Art Unit

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-912)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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#### **DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment/Remarks filed 1/28/2011.

Claims 13 and 15 have been amended. Claim 1-12 and 19 were previously cancelled.

No claims have been newly added. Accordingly, claims 13-18 remain pending in the application and are currently under examination.

#### **WITHDRAWN REJECTIONS**

Applicant's amendment renders the rejection of claim 15 under 35 USC 112 moot.

Specifically, applicant deleted the term "reducing" and replaced it with "milling". The antecedent basis issue has been resolved. Thus, said rejection has been withdrawn.

Applicant's arguments render the Double Patenting rejection moot. Specifically, the limitation "expanding the lower viscosity melt across a pressure drop into an expansion chamber that is at a pressure below the critical pressure of the supercritical fluid" is not claimed nor is it obvious over the claims of the instant application.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### **MAINTAINED REJECTIONS**

The following rejections have been maintained from the previous Office Action dated 11/24/2010:

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-15 and 17-18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Miyagawa et al. (JP 07-196840, Abstract only) in view of Ravve et al. (USPN 3,323,946). The rejection set forth on page 4 of the previous Office action dated 11/24/2010 is maintained for reasons of record and the commentary set forth below.

Miyagawa teaches producing polymeric particles by bringing a polymer into contact with carbon dioxide in a nearly supercritical or critical state in a pressurized extractor and then extruding the polymer melt through a die into a cooled solution between 0-90°C (abstract).

Miyagawa is silent to a milling step.

Ravve teaches reducing particle size of polymeric materials via milling in order to increase solubility (col. 8, lines 12-21). Ravve teaches particle sizes of about 12 microns (col. 8, lines 12-21).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to include milling the polymer product of Miyagawa with a reasonable expectation of success because Ravve teaches an old and well known method of reducing particle size via milling in order to increase the solubility of said polymer.

Thus, the combined teachings of Miyagawa and Ravve render the instant claims obvious.

### **Response to Arguments**

Applicant's arguments filed 1/28/2011 have been fully considered but they are not persuasive.

Applicant argues that Miyagawa does not teach a process comprising releasing the pressure within the pressure vessel to transform the melt in the pressure vessel into a solid porous mass. Applicant further argues that milling the product of Miyagawa would be counter-productive to the purpose of that invention. Applicant explains that the goal of Miyagawa is to produce particles that can later be heated to create expanded polymer foam and milling said particles to a very small size would very likely release the carbon dioxide entrained therein, making it highly unlikely that one would obtain expanded polymer foam upon heating the milled material. Applicant further argues that the references do not teach milling the solid porous mass before the temperature of the mass is permitted to rise to or above 25°C. See Remarks, pages 6-7.

In response, it is respectfully submitted that Miyagawa teaches releasing the pressure within the pressure vessel when the polymer melt is extruded. While the extrusion takes place not solely within a vessel, the end product appears to be comparable to that of the instant invention. Also, the polymer melt is kept to a temperature of between 0-90°C during extrusion. Depending on the specific excipient utilized, it would have been obvious to keep the polymer melt at a workable temperature. If the excipient becomes solid at X°C, one of ordinary skill would have kept the temperature below X°C until the end of the process and final product yielded. Further, while Miyagawa may have another intended use different than applicant, milling is a very

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old and well known process in the art to obtain desired particle sizes. Ravve is solely utilized in the rejection to show said old and well known process.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

Claim 16 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Miyagawa et al. (JP 07-196840, Abstract only) in view of Ravve et al. (USPN 3,323,946) and further in view of Barstow et al. (USPN 5,001,224). The rejection set forth on page 5 of the previous Office action dated 11/24/2010 is maintained for reasons of record and the commentary set forth below.

Miyagawa and Ravve teach the elements discussed above.

Miyagawa and Ravve are silent to the particular polymers claimed in instant claim 16 including polypeptides.

Barstow teaches reacting supercritical carbon dioxide with polypeptides (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include other polymers such as polypeptides with a reasonable expectation of success because Barstow teaches such a method is effective and less expensive (col. 1, lines 11-17).

### **Response to Arguments**

Applicant's arguments filed 1/28/2011 have been fully considered but they are not persuasive.

Applicant relies on the deficiencies of the base references, Miyagawa and Ravve.

In response, it is respectfully submitted that for the same reasons as discussed above, Applicant's arguments are found unpersuasive. Said rejection is maintained.

### ***Conclusion***

All claims have been rejected; no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi, can be reached at 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/  
Examiner, Art Unit 1617

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1617